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EXAMINER
SHAW, AMANDA MARIE

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

	Application No.	Applicant(s)
	10/765,943	NUMAJIRI, YASUYUKI
Office Action Summary	Examiner	Art Unit	
	Amanda Shaw	1634	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **3** MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>29 May 2009</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>28-33</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>28-33</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

1.   A request for continued examination under 37 CFR 1.114, including the fee set

forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this

application is eligible for continued examination under 37 CFR 1.114, and the fee set

forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action

has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 29,

2009 has been entered.

Claims 28-33 are currently pending. Claims 32 and 33 have been amended.

Withdrawn Rejections

2.   The rejection made under 35 USC 101 in section 3 of the Office Action of

January 29, 2009 is withdrawn in view of amendments to the claims.

Claim Rejections - 35 USC § 103

3.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

4.   Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Hogan (US 2002/0110823 Pub 8/2002 Filed 10/2001) in view of Kris (US

6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).

        Hogan teaches a method wherein a sample from a perioperative subject is used

to generate a genomic profile for that subject. Hogan teaches that in some

embodiments the genomic profile includes a set of markers that provide information that

can be used to determine the course of treatment (Para 0126). Hogan further teaches

that in some embodiments the genomic profile includes a set of unique genomic

identifiers (e.g., a series of polymorphic non coding SNPs) used to determine the

identity of the subject (Para 0134). Additionally Hogan teaches that in preferred

embodiments the genomic profiles are generated by hybridizing a genomic DNA sample

to a DNA microarray and detecting hybridization (Para 0167-0176 and Para 210).

Genomic DNA samples are expected to include genes suitable for personal

identification and disease related genes.   Thus Hogan teaches a method that

comprises hybridizing a solution of DNA including genes suitable for personal

identification and disease related genes to a DNA microarray with probes capable of

being used to identify a subject and probes capable of being used to check on the

health of a subject.   By reading and analyzing the hybridization pattern on the array it is

possible to determine the identity of the subject and obtain health related test

information for the subject. Hogan also teaches that after the sequence information has

been generated the information can be stored (e.g., as digital information on a portable

chip) (para 0186). Thus Hogan teaches a method further comprising recording the test

information onto a medical information card (clm 29), a method further comprising

storing the test information into a storing means (clm 31), a method further comprising

writing the test information into a memory unit (clm 32), a method further comprising

outputting the test information so that the test information is stored on a computer

readable storage medium (clm 33). Each of these limitations are essentially saying the

same thing in a different way. The teachings of Hogan (para 0186) meet each of these

limitations.

Hogan does not teach a method wherein the microarray has two separated areas

one of which is an area where probes of the first DNA probe group are arranged, and

another of which is an area where the probes of the second group are arranged.

However Kris teaches a microarray comprising a plurality of at least two discrete

regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the

time the invention was made to have modified the method of Hogan by using a

microarray that has two separated arrays as suggested by Kris. One of skill in the art

would have been motivated to use the array of Kris when practicing the method of

Hogan because the array of Kris allows one to analyze the presence of one or more

targets (i.e. genes for personal identification and disease related genes) at the same

time. From the teachings of the references, it was apparent that one of ordinary skill in

the art would have had a reasonable expectation of success in producing a microarray

with two separate areas wherein the first area contains probes for personal identification

and the second area contains probes for checking on a health condition of the subject.

Therefore, modifying the method of Hogan by using a microarray that has two

separated arrays was prima facie obvious to one of ordinary skill in the art at the time of

the invention.

Additionally Hogan does not teach a method comprising acquiring information

recorded on a medical card owned by the subject and comparing the identification

information from the microarray to the identification information on the medical card.

Further Hogan does not teach a step of displaying a warning and inhibiting the test

information from being written into the memory unit if the comparison result of the

comparison step indicates that the first identification information and the second

identification information do not match (clm 32) or an inhibiting step of displaying a

warning and inhibiting execution of the second reading step, the generation step, and

the output step if the comparison result of the comparison step indicates that first

identification information and the second identification information do not match (clm 33)

However Beecham teaches a method wherein biometric data submitted by a

user is compared to stored biometric data (column 18, lines 8-20). In the instant case

the biometric data submitted by the user is being interpreted as the identification

information from the microarray and the stored biometric data is being interpreted as the

identification information on the medical card (i.e., storage device). Beecham teaches

that when the biometric data submitted by the user matches the stored biometric data

then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a

method comprising comparing the identification information on the microarray to the

identification information on the medical card and releasing medical data when there is

a match. Beecham further teaches that when the biometric data (identification

information from the microarray) does not match stored biometric data (information on

the medical ID card) a request for new or revised biometric data is sent and no test

information is released until there is a match (col 18, lines 14-20). As such Beecham

teaches a step of displaying a warning and inhibiting the test information from being

released if the comparison result of the comparison step indicates that the first

identification information and the second identification information do not match.

Accordingly, it would have been obvious to one of ordinary skill in the art at the

time the invention was made to have modified the method of Hogan by comparing the

identification information on the microarray to the identification information on the

medical card before recording the patients test results on the medical card as

suggested by Beecham. One of skill in the art would have been motivated to make the

comparison in order to prevent someone from obtaining someone else's private medical

information.   Further it would have been obvious to inhibit the execution of the second

reading step, the generation step, and the output step if the comparison result of the

comparison step indicates that first identification information and the second

identification information do not match to also prevent someone from obtaining

someone else's privated medical information.

5.   **Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable**

over Barrett (US 2005/0064436 Filed 3/2005) in view of Kris (US 6238869 Issued

2001) and Beecham (US Patent 5876926 Issued 1999).

Barrett teaches a method wherein a SNP profile is determined for a nucleic acid

sample, where the determined SNP profiled is then employed to identify the source of

the sample, e.g., the subject or patient from which the sample was obtained. Barrett

further teaches that the sample can also be used to screen for a condition, e.g., a

disease. In some embodiments the sample is screened for a SNP profile and a disease

simultaneously using an array of probes wherein the array includes both SNP probe

features and disease probe features (para 0063).   Barrett teaches that the sample may

be genomic DNA which is expected to include genes suitable for personal identification

and disease related genes. Thus Barrett teaches a method that comprises hybridizing a

DNA sample including genes suitable for personal identification and disease related

genes to a DNA microarray with probes capable of being used to identify a subject and

probes capable of being used to check on the health of a subject.   By reading and

analyzing the hybridization pattern on the array it is possible to determine the identity of

the subject and obtain health related test information for the subject. Barrett further

teaches that after the sequence information has been generated the information can be

stored (e.g., as digital information in a database) (para 0053-0055). Thus Barrett

teaches a method further comprising recording the test information onto a medical

information card (clm 29), a method further comprising storing the test information into a

storing means (clm 31), a method further comprising writing the test information into a

memory unit (clm 32), a method further comprising outputting the test information so
that the test information in stored on a computer readable storage medium (clm 33).
Each of these limitations is essentially saying the same thing in a different way.   The
teachings of Barrett (paras 0053-0055) meet each of these limitations.

Barrett does not teach a method wherein the microarray has two separated
areas, one of which is an area where probes of the first DNA probe group are arranged,
and another of which is an area where the probes of the second group are arranged.

However Kris teaches a microarray comprising a plurality of at least two discrete
regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the
time the invention was made to have modified the method of Barrett by using a
microarray that has two separated arrays as suggested by Kris. One of skill in the art
would have been motivated to use the array of Kris when practicing the method of
Hogan because the array of Kris allows one to analyze the presence or one or more
targets (i.e. genes for personal identification and disease related genes) at the same
time. From the teachings of the references, it was apparent that one of ordinary skill in
the art would have had a reasonable expectation of success in producing a microarray
with two separate areas wherein the first area contains probes for personal identification
and the second area contains probes for checking on a health condition of the subject.
Therefore, modifying the method of Barrett by using a microarray that has two
separated arrays was prima facie obvious to one of ordinary skill in the art at the time of
the invention.

Additionally Barrett does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information from the microarray to the identification information on the medical card. Further Barrett does not teach a step of displaying a warning and inhibiting the test information from being written into the memory unit if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match (clm 32) or an inhibiting step of displaying a warning and inhibiting execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match (clm 33)

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is a match. Beecham further teaches that when the biometric data (identification information from the microarray) does not match stored biometric data (information on the medical ID card) a request for new or revised biometric data is sent and no test

information is released until there is a match (col 18, lines 14-20). As such Beecham
teaches a step of displaying a warning and inhibiting the test information from being
released if the comparison result of the comparison step indicates that the first
identification information and the second identification information do not match

Accordingly, it would have been obvious to one of ordinary skill in the art at the
time the invention was made to have modified the method of Barrett by comparing the
identification information on the microarray to the identification information on the
medical card before recording the patients test results on the medical card as
suggested by Beecham. One of skill in the art would have been motivated to make the
comparison in order to prevent someone from obtaining someone else's private medical
information. Further it would have been obvious to inhibit the execution of the second
reading step, the generation step, and the output step if the comparison result of the
comparison step indicates that first identification information and the second
identification information do not match to also prevent someone from obtaining
someone else's privated medical information.

6.   Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable
over Hashmi (US 2004/0048259 Filed 9/2002) in view of Kris (US 6238869 Issued
2001) and Beecham (US Patent 5876926 Issued 1999).

Hashmi teaches a method for genetic testing of an organism and for correlating the results of the genetic testing with a unique marker (i.e. SNP profile) that unambiguously identifies the organism (Abstract). Hashmi teaches that patients sample is contacted with a first set of probes that is used in an assay designed for genetic testing and the second set of probes is used in the determination of a molecular fingerprint (para 0089). Hashmi further teaches that the patients sample may be genomic DNA which is expected to include genes suitable for personal identification and disease related genes (para 0061). Thus Hashmi teaches a method that comprises hybridizing a DNA sample including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Hashmi further teaches that after the sequence information has been generated the information can be stored in a database (para 0131). Thus Hashmi teaches a method further comprising recording the test information onto a medical information card (clm 29), a method further comprising storing the test information into a storing means (clm 31), a method further comprising writing the test information into a memory unit (clm 32), a method further comprising outputting the test information so that the test information in stored on a computer readable storage medium (clm 33). Each of these limitations is essentially saying the same thing in a different way. The teachings of Hashmi (para 0131) meet each of these limitations.

Hashmi does not teach a method wherein the microarray has two separated areas, one of which is an area where probes of the first DNA probe group are arranged, and another of which is an area where the probes of the second group are arranged.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hashmi by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art would have been motivated to use the array of Kris when practicing the method of Hashmi because the array of Kris allows one to analyze the presence or one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject. Therefore, modifying the method of Hashmi by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Hashmi does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information from the microarray to the identification information on the medical card. Further Hashmi does not teach a step of displaying a warning and inhibiting the test

information from being written into the memory unit if the comparison result of the

comparison step indicates that the first identification information and the second

identification information do not match (clm 32) or an inhibiting step of displaying a

warning and inhibiting execution of the second reading step, the generation step, and

the output step if the comparison result of the comparison step indicates that first

identification information and the second identification information do not match (clm 33)

However Beecham teaches a method wherein biometric data submitted by a

user is compared to stored biometric data (column 18, lines 8-20). In the instant case

the biometric data submitted by the user is being interpreted as the identification

information from the microarray and the stored biometric data is being interpreted as the

identification information on the medical card. Beecham teaches that when the

biometric data submitted by the user matches the stored biometric data then the

medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method

comprising comparing the identification information on the microarray to the

identification information on the medical card and releasing medical data (the results of

the second DNA probe group) when there is a match. Beecham further teaches that

when the biometric data (identification information from the microarray) does not match

stored biometric data (information on the medical ID card) a request for new or revised

biometric data is sent and no test information is released until there is a match (col 18,

lines 14-20). As such Beecham teaches a step of displaying a warning (i.e., the request

for new or revised biometric data) and inhibiting the test information from being released

if the comparison result of the comparison step indicates that the first identification

information and the second identification information do not match

Accordingly, it would have been obvious to one of ordinary skill in the art at the

time the invention was made to have modified the method of Hashmi by comparing the

identification information on the microarray to the identification information on the

medical card before recording the patients test results on the medical card as

suggested by Beecham. One of skill in the art would have been motivated to make the

comparison in order to prevent someone from obtaining someone else's private medical

information. Further it would have been obvious to inhibit the execution of the second

reading step, the generation step, and the output step if the comparison result of the

comparison step indicates that first identification information and the second

identification information do not match to also prevent someone from obtaining

someone else's privated medical information.

Response To Arguments

8.   In the response filed May 29, 2009 the applicants traversed the rejections made

over Hogan, Barrett or Hashmi in view of Kris and Beecham. Regarding Kris the

applicants state that the reference teaches a kit having a plurality of separated regions

and supplying different samples, respectively to these regions. Therefore Kris does not

suggest or even hint at supplying the same sample to a plurality of probe regions and

obtaining ID information (personal identification) and test information (disease detection)

at the same time. Therefore applicants submit that Kris while teaching the use of a

substrate with multiple regions that do not necessarily have to be 100% identical does

not suggest using this type of configuration with a single sample to both identify the

subject and perform disease related analysis, i.e., there is no suggestion for using the

substrate of Kris in lieu of those in the other references.

This argument has been fully considered but is not persuasive.   Applicants are

reminded that this is a 103 rejection and Kris is only being relied upon to cure what is

missing in the other references. Kris teaches a surface comprising a plurality of

spatially discrete regions (Col 1. lines 55-60). As such Kris teaches a DNA microarray

that has two separated areas as required by claims. Further it is noted that Hogan,

Barrett, and Hashmi all teach hybridizing a solution of genomic DNA to probes that are

suitable for personal identification and probes that suitable for checking on a health

condition. Thus the combined references (i.e. Hogan and Kris, Barrett and Kris, and

Hashmi and Kris) teach hybridizing a DNA microarray with a solution of DNA, wherein

the DNA microarray includes a first DNA probe group that reacts with the genes suitable

for personal identification and a second DNA probe group that reacts with the disease

related genes, wherein the DNA microarray has two separated areas. The fact that Kris

alone does not teach supplying the same sample to a plurality of probe regions and

obtaining personal identification and test information is irrelevant since the combined

references teach all that is required. Further it is noted for the record that KSR

forecloses the argument that a specific teaching, suggestion or motivation is required to

support a finding of obviousness. See the recent Board decision Ex parte Smith, --

USPQ2d--, slip op. at 20, (Bd. Pat, App. & Interf. June 25, 2007) (citing KSR, 82

USPQ2d at 1396) (http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Nonetheless motivation is present and is provided. In the instant case one of skill in the

art would have been motivated to use the array of Kris when practicing the method of

Hogan because the array of Kris allows one to analyze the presence or one or more

targets (i.e. genes for personal identification and disease related genes) at the same

time.

       Further the Applicants argue that with respect to claims 32 and 33 neither of the

cited references disclose or suggest a testing method in which the hybridization state of

each DNA probe obtained from the second DNA probe group is analyzed and test

information is generated and written into a memory unit if the first and second

identification information match, but a warning is displayed and the writing is inhibited if

the identification information does not match. Also, neither reference discloses or

suggests reading a second hybridization pattern of the second DNA probe group,

analyzing the hybridization state of each DNA probe obtained from the second DNA

probe group, generating test information, and outputting test information if the

identification information matches, but displaying a warning and inhibiting the reading,

analysis, generation, and output if there is no identification match. The applicants state

that Beecham merely discloses transmitting records when a biometric data match is

found.

       This argument has been fully considered but is not persuasive. Beecham

teaches a method wherein biometric data submitted by a user is compared to stored

biometric data (column 18, lines 8-20). In the instant case the biometric data submitted

by the user is being interpreted as the identification information from the microarray and

the stored biometric data is being interpreted as the identification information on the

medical card. Beecham teaches that when the biometric data submitted by the user

matches the stored biometric data then the medical data can be obtained (col 8, lines

55-65). Thus Beecham teaches a method comprising comparing the identification

information on the microarray to the identification information on the medical card and

releasing medical data when there is a match. Beecham also teaches that when the

biometric data submitted by the user does not match the stored biometric data then a

request for new or revised biometric data is sent and no test information is released until

the biometric data match (col 18, lines 14-19). In the instant case the request for new or

revised biometric data is being interpreted as a warning. Since the test information is

not released if there is no match the step of writing the test results would also be

inhibited because there would be nothing to write. Further it would be obvious to also

inhibit the second reading step, the generation step, and the output step if the

comparison step indicated that the identification information did not match because if

the test information is not going to be released then there's no point in reading,

generating, and outputting it. For these reasons the rejections are all maintained.

Conclusion

9.   No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

/Carla Myers/
Primary Examiner, Art Unit 1634